

In re Application of: Peled et al
Serial No.: 10/649,873
Filed: August 28, 2003
Office Action Mailing Date: August 6, 2007

Examiner: Bruce D. Hissong
Group Art Unit: 1646
Attorney Docket: 26732

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-54 and 56-82 are in this Application. Claims 1-52 and 56-76 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 53-54, 77-78 and 80-81 have been rejected under 35 U.S.C. § 102. Claim 55 has been canceled in a previous response. Claims 77-82 have been canceled herewith. Claims 53 and 54 have been amended herewith. New claims 83 and 84 have been added herewith.

Amendments To The Claims

35 U.S.C. § 112, 1st paragraph rejection - enablement

The Examiner has rejected claims 53-54 and 77-82 under 35 U.S.C. 112, first paragraph, regarding lack of enablement. The Examiner's rejection is respectfully traversed. Claims 77-82 have been canceled. Claims 53 and 54 have been amended. New claims 83 and 84 have been added.

Specifically, the Examiner has stated that the specification is enabling for methods of inhibiting IL-8-dependent and MIG-dependent disorders by administration of BKT-45, and inhibition of MCP-1-dependent and MIG-dependent disorders by administration of BKT-46, and that the specification provides guidance and examples showing peptide inhibitors capable of inhibiting only two of the recited chemokines.

The Examiner has further stated that the breadth of the claims is excessive regarding the claimed peptides, and that a person of ordinary skill in the art would not be able to predict which of the many possible polypeptides/peptides would function as an inhibitor of IL-8, MCP-1 and/or MIG.

Applicant wishes to note that the absence of data in the examples presented that indicates that a chemokine is inhibited by a peptide does not indicate that the chemokine is not inhibited by the peptide, only that the presence of inhibition has not

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been tested yet, except when explicitly stated otherwise. As noted in response to the Office Action of November 1, 2006 and in the accompanying Declaration under 37 CFR 1.132, Applicant has presented data demonstrating the binding of a wide variety of peptides having the abovementioned features (i.e., Family 2 peptides) to a wide variety of chemokines, including chemokines other than IL-8, MIG and MCP-1. As further noted by Applicant, the results presented demonstrate that peptides typically inhibit the chemokines to which they bind. Applicant therefore believes that one skilled in the art would be able to predict an inhibition of a chemokine by a Family 2 peptide based on the sum of the inhibition data and binding data presented in the instant application and in the abovementioned Declaration.

Notwithstanding the above, and in order to expedite prosecution, Applicant has chosen to amend claim 53 in order to recite:

"A method for treating a disease modulated through or caused by binding of a chemokine to a chemokine receptor in a subject, wherein said chemokine is selected from the group consisting of MCP-1 (monocyte chemotactic protein-1) and MIG (monokine induced by gamma interferon), the method comprising administering a pharmaceutically effective amount of a peptide having an amino acid sequence as set forth in SEQ ID NO:76."

Similarly, Applicant has introduced new claim 83, which recites:

"A method for treating a disease modulated through or caused by binding of a chemokine to a chemokine receptor in a subject, wherein said chemokine is selected from the group consisting of IL-8 (interleukin-8) and MIG, the method comprising administering a pharmaceutically effective amount of a peptide having an amino acid sequence as set forth in SEQ ID NO:64."

As a result of the amendment to claim 53, claim 54 has been amended to recite "said peptide" instead of "said therapeutic agent".

In addition, new claim 84, which depends from claim 83, has been introduced, reciting limitations corresponding to those recited in amended claim 54.

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Hence, amended claims 53 and 54 and new claims 83 and 84 recite peptides and chemokines for which the Examiner has stated that the specification is enabling for the methods to which claims 53, 54, 83 and 84 pertain.

Applicant therefore believes to have overcome the Examiner's rejection.

35 U.S.C. § 112, 1st paragraph rejection – written description

The Examiner has rejected claims 53-54 and 77-82 under 35 U.S.C. 112, first paragraph, regarding lack of written description for the genus of peptide inhibitors comprising two adjacent histidines, at least two amino acids selected from P, T, L, R, W and F, and featuring an overall positive charge. The Examiner's rejection is respectfully traversed. Claims 77-82 have been canceled. Claims 53 and 54 have been amended. New claims 83 and 84 have been added.

Specifically, the Examiner has stated that one of ordinary skill in the art would not expect that every polypeptide with the abovementioned features would function as an inhibitor of IL-8, MCP-1 or MIG, that Applicant has shown only one example of a peptide capable of inhibiting IL-8 activity, and only one capable of inhibiting MCP-1, and that these examples of two single peptides are insufficient to adequately describe the claimed genus of peptide inhibitors.

As argued hereinabove, the inhibition of a variety of chemokines by a variety of Family 2 peptides, together with the finding that Family 2 peptides typically inhibit the activity of chemokines to which they bind, indicates the inhibition of many chemokines by Family 2 peptides in general.

Notwithstanding the above, and in order to expedite the prosecution, Applicant has chosen to amend claims 53 and 54 and to add new claims 83 and 84, as described and argued in detail hereinabove.

Applicant therefore believes to have overcome the Examiner's rejection.

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35 U.S.C. § 112, 2nd paragraph rejection

The Examiner has rejected claims 53-54 and 77-82 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner's rejection is respectfully traversed. Claims 77-82 have been canceled. Claims 53 and 54 have been amended. New claims 83 and 84 have been added.

Specifically, the Examiner has stated that claim 53 recites the acronyms IL-8, MCP-1 and MIG, and that acronyms must be defined upon their first use in a claim.

As recited hereinabove, claim 53 has been amended so as to define the acronyms MCP-1 and MIG. IL-8, which is no longer recited in claim 53, is recited and defined in new claim 83, as recited hereinabove.

Applicant therefore believes to have overcome the Examiner's rejection.

35 U.S.C. § 102(b) rejection – Eriksson et al.

The Examiner has rejected claims 53-54 and 77-78 under 35 U.S.C. 102(b) as being anticipated by Eriksson et al. as set forth on pages 9-10 of the Office Action mailed on 11/1/2006. The Examiner's rejection is respectfully traversed. Claims 77 and 78 have been canceled. Claims 53 and 54 have been amended. New claims 83 and 84 have been added.

Specifically, the Examiner has stated that because the claims recite 'comprising', the claimed peptides can be larger than 20 amino acids (or 12 amino acids), provided the peptides comprise a 20 amino acid (or 12 amino acid) sequence. The Examiner has suggested using 'consisting of' language in order to limit the protein size to only about 20 amino acids.

As argued hereinabove, claim 53 has been amended so as to recite a peptide having SEQ ID NO:76. Claims 77 and 78 have been canceled.

As Eriksson et al. do not teach a peptide having SEQ ID NO:76, and are completely silent regarding a method of using such a peptide as a chemokine modulator, Applicant believes that amended claim 53, as well as claim 54 which

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depends directly therefrom, are not anticipated by Eriksson et al., and are therefore allowable.

As further argued hereinabove, new claims 83 and 84 have been added, pertaining to a method utilizing a peptide having SEQ ID NO:64.

As Eriksson et al. do not teach a peptide having SEQ ID NO:64, and are completely silent regarding a method of using such a peptide as a chemokine modulator, Applicant believes that new claims 83 and 84 are not anticipated by Eriksson et al., and are therefore allowable.

35 U.S.C. § 102(e) rejection – Kovesdi et al.

The Examiner has rejected claims 53-54 and 77-78 under 35 U.S.C. 102(e) as being anticipated by Kovesdi et al. as set forth on pages 10-11 of the Office Action mailed on 11/1/2006. The Examiner's rejection is respectfully traversed. Claims 77 and 78 have been canceled. Claims 53 and 54 have been amended. New claims 83 and 84 have been added.

Specifically, the Examiner has stated that because the claims recite 'comprising', the claimed peptides can be larger than 20 amino acids (or 12 amino acids), provided the peptides comprise a 20 amino acid (or 12 amino acid) sequence. The Examiner has suggested using 'consisting of' language in order to limit the protein size to only about 20 amino acids.

As argued hereinabove, claim 53 has been amended so as to recite a peptide having SEQ ID NO:76.

As Kovesdi et al. do not teach a peptide having SEQ ID NO:76, and are completely silent regarding a method of using such a peptide as a chemokine modulator, Applicant believes that amended claim 53, as well as claim 54 which depends directly therefrom, are not anticipated by Kovesdi et al., and are therefore allowable.

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As further argued hereinabove, new claims 83 and 84 have been added, pertaining to a method utilizing a peptide having SEQ ID NO:64.

As Kovesdi et al. do not teach a peptide having SEQ ID NO:64, and are completely silent regarding a method of using such a peptide as a chemokine modulator, Applicant believes that new claims 83 and 84 are not anticipated by Kovesdi et al., and are therefore allowable.

35 U.S.C. § 102(e) rejection – Gyuris et al.

The Examiner has rejected claims 80-81 under 35 U.S.C. 102(e) as being anticipated by Gyuris et al.

Claims 80 and 81 have been canceled, thereby rendering the Examiner's rejection moot.

In view of the above amendments and remarks it is respectfully submitted that claims 53, 54, 83 and 84 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Encl:

- Additional Claims Transmittal Fee